REMARKS

Claims 1 and 26 through 50 are pending in the application.

Claim 1 has been amended to clarify that the nail polish is intended for the treatment of psoriasis of the nail. Support for this amendment in claim 1 can be found throughout the Application as filed, specifically, for example on page 7, lines 12-19.

Applicant respectfully submits that this response does not raise new issues, but merely places the above-referenced application either in condition for allowance, or alternatively, in better form for appeal. Reexamination and reconsideration of this application, withdrawal of all rejections, and formal notification of the allowability of the pending claims are earnestly solicited in light of the remarks which follow.

Submission of Terminal Disclaimer

Claims 1 and 26 through 50 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting in light of claims 1-28 of U.S. Patent No. 6,352,686 B2. Solely to advance prosecution of the case and without addressing the merits of the rejection, Applicant herewith declares to submit a terminal disclaimer over U.S. Patent No. 6,352,686 B2 upon indication of allowance of this case.

Common Ownership

Applicant herewith confirms that the subject matter of the various claims herein was commonly owned and jointly made by the inventors Bohn and Kraemer at the time any inventions covered therein were made.

The Claimed Invention is Patentable in Light of the Art of Record

Rejection Under 35 USC § 102

Claims 1, 26, 30, 33-35, 40-45, 48, and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Bernstein (US 4250164) as evidenced by Rossomando (US 4179304). It is the Examiner's position that Bernstein teaches the application of glucocorticoids in commercial nail polish compositions for the treatment of psoriasis. Example 1 discloses a nail polish composition comprising Valisone lotion (betamethasone valerate in isopropyl alcohol and carboxy vinyl polymer) and Revlon clear nail polish. It is admitted that the reference does not explicitly disclose the constituents of the Revlon nail polish, but it is viewed that the Revlon product used in the Bernstein example contains the nail polish ingredients of the present invention. In support for this Rossomando, col. 1, line 67 -col. 2, line 6, is cited which states, "a typical nail polish formulation as sold by Revlon, Inc., of New York has the following ingredients: butyl acetate, toluene, nitrocellulose, ethyl acetate, isopropyl alcohol, toluenesulfonamide/formaldehyde resin, dibutyl phthalate, camphor... and malic acid". The method of using the composition is taught in Examples 2-4.

This rejection is traversed for the following reasons:

The Examiner uses Rossomando to evidence the (undisclosed) composition of Bernsteins Revlon clear nail polish. While Applicant acknowledges the composition disclosed at col. 1, line 67 to col. 2, line 6, Applicant whishes to emphasize that the citation in Rossomando does not refer to Revlon **clear** nail polish. Col. 1, line 67 to col. 2, line 6 in Rossomando refers to "a typical nail polish formulation as sold by Revlon". Revlon sells hundreds of nail polishes, amongst others 'clear nail polish'. Thus, it is still unclear to what nail polish Rossomando exactly refers; but it is clear that the passage in Rossomando does not specifically refer to Revlon **clear** nail polish.

While Rossomando obviously fails to provide reliable evidence for the composition of Revlon clear nail polish, there is other factual evidence on this clear nail polish. One of the present inventors – Dr. Bohn – has performed comparative testing with the mixture of Bernstein comprising Revlon clear nail polish (Example I of Bernstein). This comparative testing has been presented with and explained in detail in Applicant's last Amendment filed 12 November, 2003. Dr. Bohn's

experiments were directed to mixtures that incorporated Bernstein's preferred lotion within Revlon® clear nail polish. (The Examiner's attention is kindly directed to Dr. Bohn's Declaration, Paragraphs 6 and 7). Dr. Bohn's experiments show quite impressively that with **Revlon® clear nail polish it is not possible to obtain a stable**, pharmaceutically active **nail polish** (c.f. Dr. Bohn's Exhibit I). Obviously, the nail polish of Bernstein does not comprise the ingredients of the present invention and, accordingly, Bernstein does not anticipate the subject matter claimed in the present Application.

For the sake of completeness, even if the composition in Rossomando was taken to be the composition of Revlon clear nail polish, this would still not yield in Bernsteins composition to anticipate the subject matter of the present invention. The nail polish to which Rossomando refers to as a Revlon product necessarily contains toluenesulfonamide / formaldehyde resin in the blend since this was considered indispensable in prior art nail polishes in order to provide the requisite adhesion of the nail polish to a subject finger nail (Rossomando at col. 1, lines 5 – 10). Toluenesulfonamide / formaldehyde resin is not disclosed in the present invention as being a constituent of the nail polish for forming a stable polish.

Accordingly, Bernstein in the interpretation of Rossomando does not anticipate the subject matter claimed in the present Application.

Rejection Under 35 USC §103

Claims 36-39, 46 and 47 stand rejected under 35 USC § 103(a) as unpatentable over Bernstein (US '164) as evidenced by Rossomando (US '304) in combination with Bohn et al. (US '206). Claims 27-29, 31, 32 and 50 stand rejected under 35 USC § 103(a) as unpatentable over the combination of Bernstein (US '164) as evidenced by Rossomando (US '304) and Fredriksson (US '924).

Bohn is taken to teach the film-formers of instant claims 36 and 37. It is the Examiner's position that it would have been obvious to have modified the composition of Bernstein by substituting the nail

lacquer composition with that of Bohn, as motivated by the latter reference, because both references are directed to nail lacquer compositions for treating antifungal infections. The skilled artisan would have had a reasonable expectation of successfully producing an anti-psoriasis nail lacquer composition with similar effects.

Fredriksson is taken to teach the glucocorticoids of instant claim 27 in the amounts of claims 28 and 29 or 32. The Examiner refers to *In re* Aller to support that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." It is viewed that one or ordinary skill in the art would have modified the amount of the glucocorticoid with the motivation to make an anti-psoriasis with increased **antifungal** strength. It is viewed obvious that the skilled artisan would have discovered the optimum or workable amount of the active ingredient by routine experimentation.

Applicant refrains from reiterating the arguments presented in the last Amendment, however, would like to emphasize that all of these arguments are still valid and relies upon these arguments in this response. Specifically with respect to the unobvious-arguments relating to the Bernstein reference as a primary reference, Applicant would like to rely on page 10, last paragraph to page 16 second paragraph of Applicant's last Amendment.

Applicant respectfully submits that the secondary references do not cure the deficiencies within the primary reference. Bohn et al. is directed to nail lacquers containing at least one water insoluble film-former and at least one antimycotic agent. (Col. 2, lines 58 – 63). Exemplary water insoluble film-formers include polyvinyl acetate and the like. (Col. 2, line 61 – Col. 4, line 9). Bohn et al. further notes exemplary lacquers for the treatment of mycotic nails that include a water insoluble film former and 1-hydroxy-2-pyridone. (Col. 2, lines 10 – 20 and Col. 4, lines 10 - 15). Bohn et al., however, teaches away from a combination of film forming agents with large organic molecules (like the ones disclosed in the present invention which are much larger than those employed in Bohn et al.) by emphasizing the diffusional challenges associated with transdermal systems employing solidified drug reservoirs. ((Col. 2, lines 2 – 6) "[t]he success of

this [conventional] formulation has presumably been unsatisfactory ... because of the lack of adequate bioavailability of the active substance ... after the lacquer has dried"). Such diffusional challenges become increasingly difficult for larger molecules, e.g. the glucocorticoids of the present invention.

There would, thus, have been no motivation for one skilled in the art to employ the film forming agents of Bohn et al. in the composition of Bernstein.

However, even if the cited references were combined (which Applicant submits should not be done), the claimed stable compositions would not result. As evidenced by Dr. Bohn's declaration and Exhibit I, (supplied with Applicant's last Amendment) Bernstein's topical steroid precursors are unstable when combined with the water insoluble film formers of Bohn et al.

Consequently, neither Bernstein nor Bohn et al., considered either alone or in combination, teaches or suggests the recited stable nail polishes formed from one or more glucocorticoids, one or more physiologically tolerable solvents and one or more water-insoluble film-forming agents.

Fredricksson is generally directed to ointments containing a combination of corticosteroid, particularly halogenated corticosteroid, and 5-fluorouracil to treat psoriasis. (Col. 2, lines 43 – 44 and Col. 1, lines 44 – 50). The corticosteroid is preferably present in amounts of up to 0.1 %. (Col. 4, lines 15 – 16).

Applicant would like to point out that the invention of Fredricksson is directed to ointments for the topical treatment of psoriasis through the skin (transdermal treatment). Such ointments are said to be disadvantages in the present invention. (Specification at page 2, line 10 to page 3, line 4). Moreover, teachings in the field of transdermal treatments like Fredricksson cannot be applied to treatments through thick keratin plates like finger nails. Specifically, informations about effective amounts of the active ingredient are in no way transferable from transdermal applications to trans-keratin-plate applications.

Therefore, there was no motivation for one skilled in the art to combine the teachings of Bernstein with Fredricksson. One is dealing with applying an active ingredient through a thick keratin plate (Bernstein) and the other (Fredricksson)with the application of a compound through a (thin) skin layer. These fields of application are pharmaceutically totally different and no one skilled in the art would apply a teaching from the one field in the other, neither with respect to the kind of active ingredient nor the amount.

Consequently, the combination of references does not teach or suggest the recited nail polish comprising one or more glucocorticoids, one or more physiologically tolerable solvents and one or more water-insoluble film-forming agents, which forms a stable nail polish.

CONCLUSION

It is respectfully submitted that Applicant has made a significant and important contribution to the art, which is neither disclosed nor suggested in the art. It is believed that all of pending Claims 1 and 26 through 50 are now in condition for immediate allowance. It is requested that the Examiner telephone the undersigned if any questions remain to expedite examination of this application.

It is not believed that extensions of time or fees are required, beyond those which may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time and/or fees are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required is hereby authorized to be charged to Deposit Account No. 50-2193.

Respectfully submitted,

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Page: 12

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